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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/647,625

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Eva Vranova

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EXAMINER

DUNSTON, JENNIFER ANN

ART UNIT

PAPER NUMBER

1636

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/647,625

Applicant(s)

VRANOVA ET AL.

Examiner

Jennifer Dunston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,9-11,14,15 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) 11,14,15,19,20,22 and 23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 is/are allowed.
- 6) ☒ Claim(s) 9,10,18,21 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

This action is in response to the amendment, filed 1/22/2007, in which claims 1-5, 7-8, 12-13 and 16-17 were canceled, claims 6, 9, 10-11, 14-15, 18 and 21 were amended, and claim 24 was newly added. Currently, claims 6, 9-11, 14-15 and 18-24 are pending.

Applicant's arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and objections not reiterated in this action have been withdrawn. **This action is FINAL.**

Election/Restrictions

Applicant elected Group I and SEQ ID NOS: 168 and 169 without traverse in the reply filed on 7/31/2006.

Claims 11, 14-15, 19-20 and 22-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/31/2006.

Currently, claims 6, 9-10, 18, 21 and 24 are under consideration.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Receipt of the certified copy of the foreign priority document, EPO 01200659.9, is acknowledged. These papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the product of claim 18 are unclear. Claim 18 depends from claim 9, which requires a promoter operably linked to a nucleic acid encoding a polypeptide having at least 90% identity with SEQ ID NO: 169. The nucleic acid encoding the polypeptide is obtained as a product produced by the claimed process. Claim 18 is drawn to steps of isolating the endogenous promoter from genomic DNA comprising a nucleic acid encoding a polypeptide of at least 90% identity to SEQ ID NO: 169. It is unclear if this promoter is the promoter to be operably linked to the coding nucleic acid. The claim does not specify the relationship of the promoter from the genomic DNA to the promoter of the isolated polynucleotide. Thus, the metes and bounds of the claim are unclear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 18, 21 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The claims are drawn to or encompass a polynucleotide encoding a polypeptide having at least 90% identity with SEQ ID NO: 169.

The response asserts that support for the amendments can be found throughout the specification, especially paragraph [0017], and in original claims 6 and 7.

The specification does not provide support for nucleic acid molecules or polynucleotides encoding a polypeptide with at least 90% identity to SEQ ID NO: 169. The specification describes the polypeptide SEQ ID NO: 169, one member of the claimed genus. The specification envisions genes and gene fragments (polynucleotides or nucleic acid molecules) with 90% identity to SEQ ID NO: 168 (e.g., paragraph [0017]). However, percent identity between two nucleic acid molecules is not equivalent to percent identity between two proteins due to the degeneracy of the genetic code. The specification as filed fails to provide support for nucleic acid molecules that encode proteins that are at least 90% identical to SEQ ID NO: 169 (i.e., protein-protein comparison).

The original specification, drawings and claims were thoroughly reviewed and no support could be found for the amendment. Accordingly, the amendment is a departure from the specification and claims as originally filed, and the passages that Applicant has provided do not provide support.

Claims 9, 10, 18, 21 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new rejection, necessitated by the amendment to the claims in the reply filed 1/22/2007.

Claim 9 is drawn to a genus of polynucleotides, comprising a promoter operably linked to a nucleic acid encoding a polypeptide having at least 90% identity with SEQ ID NO: 169. The claim does not require the percent identity to be over the entire length of SEQ ID NO: 169. Thus, the claim encompasses fragments with at least 90% identity to a portion of SEQ ID NO: 169. Further, the claim requires the polynucleotide to be differentially expressed between stress-adapted and nonadapted plant material of any species of plant. Claim 18 further requires the polynucleotide to comprise a promoter of the differentially expressed polynucleotide. Claim 21 requires the nucleic acid of claim 9 to be present in a vector. Thus, the claims encompass a genus of polynucleotides obtained from any species of plant organism defined by the ability to encode a protein that is at least 90% identical to SEQ ID NO: 169, where the polynucleotide is differentially expressed between stress-adapted and non-adapted plants.

Claim 24 is drawn to a genus of nucleic acid encoding a polypeptide having at least 90% identity to SEQ ID NO: 169. The claim does not require the polynucleotide to have any particular function; however, the only disclosed use for the nucleic acid is modulating stress tolerance in a plant. Thus, the claim encompasses a genus of nucleic acid molecules defined by percent identity.

Claim 10 is drawn to a genus of polynucleotides, comprising a promoter operably linked to a polynucleotide having at least 90% identity with SEQ ID NO: 168. Further, the claim

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requires the polynucleotide to be differentially expressed between stress-adapted and nonadapted plant material of any species of plant. Thus, the claim encompasses a genus of polynucleotides that are defined by percent identity and must be differentially expressed between stress-adapted and nonadapted plants.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification envisions the isolation of differentially expressed genes or gene fragments from any plant material by any type of stress (biotic or abiotic) (e.g. paragraphs [0009]-[0011]). The specification envisions using techniques such as differential display, messenger RNA subtraction, filter hybridization or micro-array techniques to identify the differentially expressed transcripts (e.g. paragraph [0012]). The specification teaches the application of methyl viologen (MV) to leaf tissue of *Nicotiana tabacum*, and the identification of approximately 170 partial expressed sequences that are induced or repressed upon stress adaptation by MV (e.g. paragraph [0008], [0036]-[0039] and [0051]; Table 1). Expression of 16 genes was analyzed by Northern analysis with RNA from and independent experiment, and the induction of 12 genes was confirmed (e.g. paragraph [0051]). Thus, four of the sixteen genes were not confirmed. Accordingly, the specification describes twelve sequences that are induced in tobacco leaves upon exposure to MV: SEQ ID NOS: 52, 66, 106, 117, 131, 137, 138, 143, 148, 149, 142 and 160 (e.g. Table 2). SEQ ID NO: 117 is contained within the full-length cDNA

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of SEQ ID NO: 168, which encodes the protein of SEQ ID NO: 169 (e.g. Table 2, sequence listing, and Example V).

With regard to promoter sequences, the specification envisions using methods known in the art to identify the promoter sequences of the differentially expressed sequences (e.g. paragraph [0018]). The specification does not teach the isolation of any promoter sequence for any of the 167 partial cDNA sequences obtained in the MV assay. There is no known or disclosed correlation between the claimed differential expression and the structure of the regulatory elements of those genes that are differentially expressed. Furthermore, there is no disclosure of the promoter sequences.

The claims encompass nucleic acid molecules and polypeptides that are homologs of the nucleic acid molecule of SEQ ID NO: 168 and polypeptide of SEQ ID NO: 169. However, the prior art teaches that different cultivars can have different responses to stresses. Martinez et al (Plant Science, Vol. 160, pages 505-515, February 5, 2001, cited in a prior action) teach that *Solanum curtilobum* has markedly increased activities of FeSOD and Cu/ZnSOD with increasing level of PEG-induced water stress or MV-mediated oxidative stress, whereas *Solanum tuberosum* has unaltered levels of SOD activities in response to water stress and markedly decreases MnSOD and Cu/ZnSOD activities in response to MV-mediated oxidative stress (e.g. page 512, paragraph bridging columns). Thus, one would not expect homologs of SEQ ID NOS: 168 and 169 to necessarily have the same function across cultivars or species.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry,

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whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of differentially expressed sequences and promoter sequences thereof, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGFs were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

"A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004). In the instant case, one could not predict the operability of sequences other than SEQ ID NO: 168 and sequences encoding SEQ ID NO: 169. The specification does not provide specific guidance with regard to a structure/function correlation, and the orthologous sequences in other cultivars or species will not necessarily have the same function.

Given the genus of differentially expressed sequences and promoters thereof encompassed by the rejected claims, and given the limited description provided by the prior art and specification with regard to a common structure within the genus, the skilled artisan would not have been able to envision a sufficient number of specific embodiments that meet the functional limitations of the claims to describe the broadly claimed genus. Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision a representative number of differentially expressed sequences and promoters that satisfy the functional limitations of the claims. Therefore, the skilled artisan would have reasonably concluded applicants were not in possession of the claimed invention for claims 9, 10, 18, 21 and 24.

Response to Arguments - 35 USC § 112

The rejection of claims 6, 7, 9, 10, 18 and 21 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of Applicant's amendment to the claims in the reply filed 1/22/2007.

With respect to the rejection of claims 9, 10, 18, 21 and 24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, Applicant's arguments filed 1/22/2007 have been fully considered but they are not persuasive.

The response essentially asserts that the provision of SEQ ID NOS: 168 and 169 and the discussion at paragraph [0017] of the specification adequately describes the claimed invention. This is not found persuasive, because no structural/functional correlation has been provided, and sequences obtained from other cultivars or species of plants will not necessarily have the same function.

For these reasons, the rejection under 35 U.S.C. 112, first paragraph is presented above.

Response to Arguments - 35 USC § 102

The rejection of claims 7 and 18 under 35 U.S.C. 102(b) as being anticipated by Chen et al has been withdrawn in view of Applicant's amendment to the claims in the reply filed 1/22/2007.

The rejection of claims 7 and 21 under 35 U.S.C. 102(b) as being anticipated by Deruere et al, as evidenced by Chen et al, has been withdrawn in view of Applicant's amendment to the claims in the reply filed 1/22/2007.

The rejection of claims 7 and 21 under 35 U.S.C. 102(b) as being anticipated by Hiraga et al has been withdrawn in view of Applicant's amendment to the claims in the reply filed 1/22/2007.

The rejection of claims 7 and 21 under 35 U.S.C. 102(b) as being anticipated by Chen and Chen has been withdrawn in view of Applicant's amendment to the claims in the reply filed 1/22/2007.

The rejection of claim 7 under 35 U.S.C. 102(b) as being anticipated by GenBank Accession No. X66942 has been withdrawn in view of Applicant's amendment to the claims in the reply filed 1/22/2007.

Conclusion

Claim 6 is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached at 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

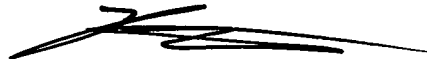
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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.
Examiner
Art Unit 1636

jad

CELINE QIAN, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'C. Qian', written over the printed name of the Primary Examiner.